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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,738	12/09/2003	Brian K. Shoichet	7375	5161

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,738

Applicant(s)

SHOICHET ET AL.

Examiner

Susannah Chung

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7,8,11,28 and 29 is/are rejected.
- 7) ☒ Claim(s) 3,12,30,31,33 and 34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date ____.

- 4) ☒ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. 010306.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-12 and 28-34 are pending in the instant application. Claims 13-27 have been canceled by amendment filed on 08/11/2005.

Response

Applicant's response filed on 08/11/2005 is acknowledged.

35 U.S.C. 103(a) Rejection

Claims 28 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al., "Structures of Ceftazidime and Its Transition-State Analogue in Complex with AmpC β -Lactamase: Implications for Resistance Mutations and Inhibitor Design," Biochemistry, 40, 9207-9214, published on web 07/10/2001. Applicants arguments have been considered and are found unpersuasive. Examiner agrees that the difference between the prior art of Powers and the claims is that in the instant application there is substitution, i.e. a methyl group, off the carbon alpha to the boron, while in the prior it is hydrogen. Although, applicant's compound differs in that it has a methyl instead of a hydrogen group off the carbon alpha to the boron, it is well known in the art that hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137. Therefore, the 103 rejection of claims 28 and 29 stand.

In addition, Claims 28 and 29 use the transitional phrase "comprising" or "comprises" which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP §2111.03, ¶2 (Rev. 3 (August 2005)). The term comprising leaves the claim open for the inclusion of unspecified ingredient even in major amounts. Therefore, the compound of Powers, which is unsubstituted, could be included in the composition.

35 U.S.C. 112 Rejection

The rejection of Claim 34 under 35 U.S.C. 112 is withdrawn.

Rejoinder

Claims 1-12 are rejoined.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The term “heterocyclyl” of Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32.

In addition, Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification although enabling for certain “heterocyclyl” moieties (Claim 6 and Specification, p. 7, paragraph 2), it is not enabling to make or use the vast number of other potential “heterocyclyl” compounds without an undue amount of experimentation for the reasons described below.

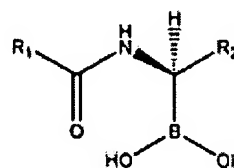
As stated in MPEP 2164.01(a), “there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.”

The factors to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, were described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as:

1. the nature of the invention;
2. the breadth of the claims;
3. the state of the prior art;
4. the relative skill of those in the art;
5. the predictability or unpredictability of the art;
6. the amount of direction or guidance presented (by the inventor);
7. the presence or absence of working examples; and
8. the quantity of experimentation necessary (to make and/or use the invention).

The eight Wands factors are applied to Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 of the present invention below:

(1) The Nature of the Invention



The nature of the invention is a compound of the formula,

(2) The Breadth of the claims

The breadth of independent Claims 1, 6, 10, and 28 and dependent claims 2, 4, 7, 8, 11, 29, and 32 encompass products of all chemical compounds, which are “4-10 membered heterocyclic ring containing one or more heteroatoms, including but not limited to oxygen, nitrogen, or sulfur,” (see specification page 7, lines 10-12). However, Claims 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 do not recite a chemical structure (or written equivalent) which expressly defines the heterocyclyl ring structure.

The claims do not specify or enumerate which of the many types of “4-10 membered heterocyclic ring containing one or more heteroatoms, including but not limited to oxygen, nitrogen, or sulfur,” fall within its scope. The applicable rule for interpreting the claims is that “each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.” See MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In view of this rule, the products of Claim 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 may reasonably be interpreted to encompass *all* 4-10 membered heteroaromatic ring which may contain any number of heteroatoms from the group of N, O, and S, etc... as the specification does not limit or define the products to a closed set of products.

(3) The state of the prior art

Certain cyclic and heterocyclic compounds are known β -lactamase inhibitors. (See specification, pages 1-2).

(4) The relative skill of those in the art

The level of skill in the art (pharmaceutical chemists, physicians) would be high.

(5) The predictability or unpredictability of the art

As demonstrated earlier, the compound claimed in the instant application, wherein R1 can be any heterocyclyl includes an extremely large scope of the potential products as encompassed by Claim 1, 2, 4, 5, 7, 8, 11, 28, 29, and 32 rendering the prior art unpredictable for making or using products as claimed on such a grand scale.

(6) The amount of direction or guidance presented (by the inventor)

The specification in the present invention discloses chemical examples of the species of preferred compounds, where the heterocyclyl ring is thiophenyl, oxazolyl, pyrimidyl, etc.... (See Claims 6, 10, etc...)

(7) The presence or absence of working examples

As noted in the previous section, the specification discloses the general role of the compound of claim 1. However, the specification has no working examples of where the core compound is anything but those depicted in the claims.

(8) The quantity of experimentation necessary (to make and/or use the invention)

Given the absence of direction or guidance (or working examples) in the specification for any of the extremely large number of compounds that would be encompassed by the descriptions “heterocyclyl” it would cause a skilled artisan an undue amount of experimentation to determine which product the process of making was describing. Also, a skilled artisan would not be able to predict which “heterocyclyl” compound would be useful as β -lactamase inhibitors.

Applicant may overcome this rejection by deleting the term “heterocyclyl.”

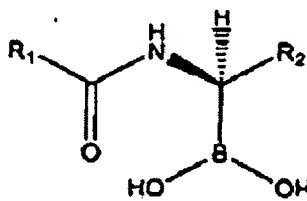
Objections

Claims 30-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7, 8, and 11 are objected to as not limited another claim from which it depended. This objection can be obviated by deleting the term “heterocyclyl.”

Reasons for Allowance

The present invention is directed to β -lactamase inhibitor compounds and compositions of a



formula,

. The closest prior art of record is Powers et al., “Structures of Ceftazidime and Its Transition-State Analogue in Complex with AmpC β -Lactamase: Implications for

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Resistance Mutations and Inhibitor Design," Biochemistry, 40, 9207-9214, published on web 07/10/2001, which teach similar β -lactamase inhibitor compounds and compositions, except that in the instant application there is substitution alpha to boron, while in the prior art it is unsubstituted.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
Patent Examiner, AU 1626

Date: 01/03/2006

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PRIMARY EXAMINER